



AMERICAN
SUSTAINABLE
BUSINESS
COUNCIL

April 1, 2019

Congressman Frank Pallone
237 Cannon House Office Building
Washington, DC 20515

Congressman John Shimkus
2217 Rayburn House Office Building
Washington, DC 20515

Re: Public Comment on the Cosmetic Safety Enhancement Act of 2019

From: Businesses supporting comprehensive, health-protective federal cosmetic safety policy reform

Dear Congressman Pallone and Shimkus:

The undersigned 50 businesses support strong, health protective, comprehensive federal cosmetic safety policy reform that protects consumers and workers and levels the playing field for companies who are committed to making and selling beauty and personal care products that are safe for people and the planet. With strengthening amendments in key areas, we believe the Cosmetic Safety Enhancement Act of 2019 can be an important step forward in effectively regulating the cosmetics industry and protecting public health.

Some companies are committed to ensuring the chemicals the industry uses to formulate cosmetics are safe for long term health. But other companies – both large and small – treat cosmetic safety as if it's the Wild West using ingredients with known health hazards, including chemicals linked to cancer, reproductive harm, birth defects, learning disabilities, respiratory harm, and endocrine disruption.

Taken alone, chemicals in any one cosmetic product may not cause harm. Unfortunately, we know that people are repeatedly exposed to industrial chemicals from many different sources, including multiple beauty and personal care products, on a daily basis. The combined exposure from personal care products adds to the daily exposure the public faces from hazardous chemicals in our air, water, food and other consumer products. These chemicals end up in the bodies of our customers, their breast milk and their children; they contaminate drinking water and wildlife; and some persistent chemicals build up in the food chain.

Companies like ours want to be a part of the solution by making products without toxic chemicals that do not pollute people and the planet.

This is not a niche market, its big business. Natural, safe and clean beauty products represent the fastest-growing segment of the personal care product market, and retail sales of this segment are estimated to generate [\\$15.6 billion](#) by the end of 2020. This growth in the safe cosmetics industry is due to increasing consumer knowledge about hazardous chemicals in cosmetics and growing consumer demand for safe cosmetics.

The sustainable, natural/clean cosmetics industry has responded by making non-toxic products and offering full ingredient transparency. If a company stands by the safety of the ingredients in their products, then publicly disclosing all ingredients— including fragrance, flavorings and colorants – should not be a problem.

Consumers are seeking safer food, non-toxic carpets, paints, building materials, toys and cleaning products. Not surprisingly, consumers are also seeking safer personal care products without chemicals linked to cancer and other adverse health effects, and with strengthening changes, your bill can help them shop with the confidence they deserve.

Areas where the Pallone-Shimkus Discussion Draft Needs Strengthening

The undersigned companies believe your bill would better protect consumer and worker health and serve sustainable businesses by:

- Expanding and strengthening the breadth and depth of the bill's safety standard;
- Requiring full fragrance, flavor and colorant ingredient disclosure to the FDA, manufacturers, and consumers;
- Requiring industry data sharing of safety studies to assist small businesses and decrease animal testing;
- Mandating supply chain transparency so companies have access to the ingredient information and safety data they need to make safer products;
- Ensuring consumers have easy access to adverse event reports related to cosmetic products that are causing hair loss, respiratory harm, burns, disfigurement, hospitalization, harm to maternal health or other adverse reactions;
- Protecting the ability of the states to legislate on cosmetic safety; and
- Removing the \$20.6 million cap on fee revenue that can be generated to support FDA's expanded cosmetic safety program and creating a true sliding scale fee structure that is prorated based on the establishment's gross revenue.

1. Support special allowances for small businesses to comply with new cosmetic safety statutory requirements.

We support special allowances for small businesses to meet the expanded regulatory demands addressed by your draft bill. Specifically, we support allowing companies that make \$1 million or less to submit simplified statements and be given more time to comply with program requirements.

2. Require full fragrance ingredient disclosure to the FDA, manufacturers, and consumers

No federal law requires the disclosure of fragrance or flavor ingredients in personal care and beauty products to consumers, workers, manufacturers or even regulatory agencies. This loophole allows dozens – sometimes even hundreds – of chemicals to hide under the word “fragrance” on the labels of cosmetic products with no regulatory oversight of the safety of those ingredients. Fragrance chemicals can be found in more than 95% of shampoos, conditioners, hair styling products, antiperspirants and shaving products as well as fine fragrances, body spray and lotions. One third of the fragrance chemicals currently in use have been linked to negative health impacts ranging from allergic reactions to reproductive harm and increased risk of breast cancer. The same loophole exists for chemicals used to flavor a product, which are appearing more and more frequently in lip gloss and chap sticks marketed to kids.

In response to consumer and worker right to know demands, hundreds of cosmetic companies are already voluntarily disclosing fragrance ingredients. Honest labeling and full disclosure will help consumers make informed choices, and benefit companies that embrace transparency.

Your discussion draft should require manufacturers to disclose the specific fragrance ingredients in a finished cosmetic product to the FDA without the agency having to file a request to see these ingredients. The FDA cannot prioritize cosmetic chemical testing by frequency of use without full fragrance ingredient disclosure from the outset.

Your bill should also require fragrance houses to provide full fragrance ingredient disclosure to the companies for whom they make and sell their fragrance formulations. Manufacturers cannot substantiate the safety of all of the ingredients in a product without full ingredient disclosure from their fragrance suppliers. And finally, your bill should require companies

to provide full fragrance ingredient disclosure to the public: consumers and workers cannot protect themselves from unsafe fragrance chemical exposures if they do not know what fragrance ingredients they are being exposed to.

3. Strengthen the breadth and depth of the bill's safety standard

The safety standard in your discussion draft should be strengthened to ensure children, pregnant women, workers and other vulnerable populations are not harmed by unsafe chemicals in beauty and personal care products.

It is problematic that your discussion draft's safety standard only applies to the FDA's assessment of 5 ingredients per year, not to cosmetic manufacturers themselves who are responsible for the lion's share of ingredient safety substantiation. We support strengthening the safety standard in your draft bill and requiring manufacturers to adhere to and follow the same safety substantiation guidelines as the FDA. In addition, your draft bill allows cosmetic companies to attest to the safety of the cosmetic chemicals in their products by referencing science generated by industry-funded entities (such as the Cosmetic Ingredient Review and Research Institute for Fragrance Materials), and allows those entities to be identified as "authoritative bodies" on par with well-respected, scientific bodies such as the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC). The bill's definition of "official bodies" should be amended to include only authentic authoritative scientific bodies that make their safety studies publicly available and do not accept industry funding, so as to avoid a conflict of interest.

In addition, your discussion draft does not specifically direct the FDA or manufacturers to consider long term effects of ingredient use, including links to cancer, reproductive, and developmental harm. A clear directive to consider long term, chronic health endpoints is necessary to prevent ingredient safety assessments from being conducted solely based on the presence or absence of acute reactions.

4. Increase Transparency along the Cosmetic Industry Supply Chain

The natural, safe and clean cosmetics industry will benefit from federal rules and regulations that will help them make truly safer and more sustainable products. We need federal legislation that increases transparency along the entire supply chain by requiring suppliers of fragrance, preservatives and raw materials to fully disclose ingredients, contaminants and safety data for these materials so cosmetic companies can provide a higher level of transparency to consumers and workers. By doing so, cosmetic companies will also generate a higher level of confidence regarding the safety of our products. As recent court settlements have demonstrated, companies face liability from health hazards directly caused by or linked to unsafe chemicals in their products. Cosmetics companies must be able to trust upstream suppliers, and have confidence that the ingredients, raw materials, fragrance and flavor formulations and finished products they produce are safe.

Your bill should require full transparency and greater accountability along the supply chain by requiring suppliers of fragrance, preservatives and raw materials – and formulating labs – to fully disclose ingredients, contaminants and safety data for these materials and finished products. Only then will cosmetic manufacturers be able to fully substantiate the safety of their products and provide a higher level of transparency to consumers. Cosmetic companies cannot ensure the safety of their products if they are not able to reliably access ingredient and safety data from their suppliers.

5. Require industry data sharing

Your bill should direct the FDA to create a database of safety studies generated by companies, scientific authoritative bodies and state, federal and world governments relevant to the chemicals used to formulate cosmetics. It should also require industry data sharing of safety studies in order to reduce animal testing, help small businesses and expedite FDA safety substantiation of cosmetic chemicals.

6. Require adverse event reporting and make these reports available to the public

Consumers have a right to know if a cosmetic product causes adverse reactions, just as they currently have access to know this information regarding contaminated or unsafe food, drugs, medical devices and toys.

Your bill should make serious adverse event reports easily and readily available to the public. Requiring consumers to submit a freedom of information act request to access adverse event reports related to commonly used cosmetic and personal care products is an unreasonable hurdle for most people.

7. Eliminate the federal preemption clause

Your bill should not prohibit States from enacting legislation to address good manufacturing processes, product recalls, and adverse events reporting. Nor should it bar states from prohibiting cosmetic chemicals under FDA review.

Individual States, rather than the Federal government, have led the way in passing environmental health protections, and should maintain the right to protect citizens from unsafe chemical exposure. We need a floor for cosmetic safety to ensure that public health is protected and to increase consumer confidence, but there's plenty of room for continuous improvement at the top.

Consumers need to be able to trust that the beauty and personal care products on store shelves meet a basic level of safety, and not everyone can afford or has access to safer alternatives entering the market. Setting a bottom line of safety is what other countries around the world are doing now and this builds consumer confidence. However, establishing a floor of basic safety protections doesn't mean there should be a ceiling that limits our ability to require even safer, more sustainable and efficacious products, which consumers are demanding.

8. Animal Testing Alternatives.

We support retaining the bracketed animal testing language in Section 108 would encourage the use of alternative testing methods, the sharing of data so as to avoid duplication of animal tests, the publication of resources regarding non-animal testing methods and the issuance of guidance by the FDA regarding the acceptability of scientifically reliable, validated and relevant alternatives to animal testing for the safety of cosmetic ingredients, contaminants and finished cosmetic products.

9. Eliminate the \$20.6 million cap on fees that can be generated to support the FDA's expanded cosmetic safety program.

If the FDA is to be successful in meeting the expanded statutory obligations included in your discussion draft, they must be given the resources needed to hire the necessary staff and build the required infrastructure to succeed. Therefore, we urge you to remove the \$20.6 million cap on fees that can be generated to support the FDA's safe cosmetics program and create a true sliding scale fee structure that is prorated based on the establishment's gross revenue.

In closing, we deeply appreciate the opportunity to comment on this discussion draft and stand ready to work with you to craft the most health protective legislation possible. Thank you for your leadership on this important consumer health, worker health and business sustainability issue and for your consideration of our public comment. With these important strengthening changes, the Cosmetic Safety Enhancement Act of 2019 can realize its full potential and truly protect consumers, workers and other vulnerable populations from dangerous chemicals in personal care products and restore their confidence in the safety of cosmetic products.

For more information, please contact: David Levine, Cofounder & President, American Sustainable Business Council, dlevine@asbcouncil.org, 202-595-9302 x101

Listing of Business Signatories

American Sustainable Business Council
Campaign for Safe Cosmetics Safe Cosmetics Business Network
100% PURE
Affordable Mineral Makeup
Ajara Life Systems Inc
Aroma Naturals
Beauty by Upfront Distribution
Beleza Organica
Brand Geek
California Baby
Climate Social, LLC
Communitas Financial Planning
Crunchi, LLC
Dr. Bronner's
Earth Mama Organics
Ecco Bella
EcoPlum, Inc
Eighty2degrees Design Studio
Elavo Mundi Solutions, LLC
EO Products
Equinox Consultancy LLC
Essential Skincare
Free of, inc
Future 500
HAN Skincare Cosmetics
Happy Pretty You! Reiki Salon & Spa
inHarmony Naturals
Innersense Organic Beauty
Intelligent Nutrients
Juice Beauty
Just the Goods
Lauren Brooke Cosmetiques
My Sister's Natural, LLC
Nia Impact Capital
North American Climate, Conservation and Environment(NACCE)
One Earth Ventures Inc.
OSEA Malibu
Oz Naturals
OZNaturals Skincare
Palette & Parlor
Pour le Monde Natural Perfumes
Purified7x
SAI
Seventh Generation
Seriously FAB LLC
Sustainable Works
Suzanne's Organics Salon
The Holistic Health Co.
Toogga
Trillium Organics
Wolf, DiMatteo + Associates
Zorah biocosmétiques